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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,327	12/01/2000	Glen Jorgensen	ZQI-102 US B-CONI	4739
48329	7590	12/22/2005	EXAMINER	
FOLEY & LARDNER LLP 111 HUNTINGTON AVENUE 26TH FLOOR BOSTON, MA 02199-7610			MILLER, MARINA I	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,327

Applicant(s)

JORGENSEN ET AL.

Examiner

Marina Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 37-55 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Applicants' submission filed on 9/23/2005 is acknowledged. Claims 37-55 are pending. Claims 1-36 are cancelled. Claims 37-55 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments with respect to claims 37 and 52 have been considered but are moot in view of the new ground(s) of rejection.

Claims 37 and 53 recite the limitation the "environmentally closed" system. The instant claims are vague and indefinite because it is not clear whether the system is closed to input/output from/to outside (*e.g.*, sample input/output, chemicals, contamination, *etc.*), or closed into a chamber with specific conditions (*e.g.*, vacuum, temperature, or humidity), or whether the system is intended to be one which allows only input of sterile components. Neither the claims nor the specification defines an "environmentally closed" system. As the intended limitation is not clear, claims 37 and 55 are indefinite. Claims 38-52 and 54-55 depend from claims 37 and 53, respectively, and theretofore are indefinite.

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Claims 42 and 50 recite “an in-line filter.” It is not clear whether the filter is physically positioned (*e.g.*, on a straight line) between two modules or the filter filtrates fluid while it passes from a supply module to a processing module (and therefore is called “in-line”). As the intended limitation is not clear, claims 42 and 50 are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37-41, 44-49, and 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, US 6,544,727, in view of Inoue, US 5,153,828.

Applicant's arguments with respect to claims 37-55 have been considered but are moot in view of the new ground(s) of rejection.

Hei discloses a system for the decontamination biological fluids (*e.g.*, blood) (abstract and col. 66-68). Hei discloses a supply module (fig. 51, elements 508, 539, and 560). Hei discloses a cell module (fig. 51, elements 500, 528, and 538). Hei discloses a processing module (*e.g.*, element 538 of fig. 51; a block disclosed on fig. 1 and 3; an element where blood and a chemical is mixed on fig. 20B-C). Hei discloses a control module (fig. 51, element 550). Hei discloses a plurality of conduits connecting the supply module to the processing module, and the cell module to the processing module (fig. 49-51 and 20A-C). Hei discloses a plurality of valves adapted to the control module and other modules (ports, *see* fig. 49-51, 20A-C, and 37). Hei discloses a plurality of sensors, and specifically a sensor calculating the volume and weight of

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fluids (col. 65, line 30-47). Hei disclose controlling temperature (col. 71, line 63-65; col. 72, line 55-64), flow (col. 66, line 40-65) and volume (col. 68, line 14-40) and an optical device (col. 100, line 28-38). Hei discloses supply containers containing process chemicals (fig. 20, 37, and 49-51; col. 68, line 14-67). Hei discloses phosphate salts, HEPES, citrates, physiological buffers, and anticoagulants (col. 69-70, col. 66, line 40-44). Hei discloses sterile docking, sterile filters, resin (chemical), sterile bags, sterile tubes, sterile tubing, and housing (col. 97, line 29-38 and claim 28). Hei discloses an in-line filter (claims 1 and 21). Hei discloses a centrifuge system (fig. 49-51, element 520). Hei discloses a heat transfer system (col. 72, line 53-67). Hei discloses processing chamber (element 538, fig. 51 and fig. 1). Hei discloses variable volume processing chamber (fig. 20 and 37; col. 97, line 40-65). Hei discloses an expression system (col. 97, line 40-67). Hei discloses an air module (col. 73, line 1-3). Hei discloses a waste module (a mesh pouch) (col. 121, line 45-61). Hei discloses pumps (elements 516, 506, 536, 526, and 556 of fig. 51). Hei discloses the blood cells as being erythrocytes (col. 12, line 18).

Although Hei discloses sensors for calculating weight and volume of reinfused fluids and defining quantity of blood cells (col. 68, line 14-24; col. col. 65, line 30-47), Hei does not specifically disclose a weight sensor.

Inoue discloses an apparatus for collecting blood comprising a control device and a measuring collected blood device (weight sensor) (abstract, col. 5, line 39-50).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the system of Hei to use a weight measuring sensor, such as taught by Inoue, where the motivation would have been to improve accuracy of the procedure, as taught by Inoue, col. 2, line 26-29.

Claims 42-43 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, US 6,544,727, in view of Inoue, US 5,153,828, as applied to claims 37-41, 44-49, and 51-54 above, and further in view of Matkovich, US 5,126,054.

Hei and Inoue make obvious the system of claims 37-41, 44-49, and 51-54, as set forth above.

Hei discloses an in-line filter (claims 1 and 21), but Hei and Inoue do not disclose an in-line filter having a median pore diameter of about 0.2 microns and a leukocyte depletion filter.

Matkovich discloses the in-line filtration of blood components into a receiving bag (col. 1, line 13-17 and claim 1). Matkovich further discloses removing leukocytes by filtration from blood (leukocyte depletion) (col. 1, line 13-17; col. 5-6, bridging paragraph). Matkovich discloses a filter having 0.2 micron pores (claims 5 and 10).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the system of Hei and Inoue to use a filter to deplete leukocytes, such as taught by Matkovich, where the motivation would have been to remove harmful components, as taught by Matkovich, col. 6, line 5-9.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, US 6,544,727, in view of Inoue, US 5,153,828, as applied to claims 37-41, 44-49, and 51-54 above, and further in view of Hudak, US 5,641,637.

Hei and Inoue make obvious the system of claims 37-41, 44-49, and 51-54, as set forth above.

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Hei and Inoue do not disclose the blood cell genotypes A, B, or AB.

Hudak discloses a method for preparing cells. Specifically, Hudak discloses rare genotype cells (*e.g.*, AB genotype) (col. 2, line 45-52).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the system of Hei and Inoue to use AB cells, such as taught by Hudak, where the motivation would have been to provide hospitals with rare cell genotype blood, as taught by Hudak, col. 2, line 45-52.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller
Examiner
Art Unit 1631

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
12/19/05

MM